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| 09/807,402 | 08/03/2001 | Peter Hofert | SCH 1808 | 9208 |

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EXAMINER

MAIER, LEIGH C

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1623

DATE MAILED: 06/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/807,402

Applicant(s)
Hofert

Examiner
Leigh Maier

Art Unit
1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 5, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) 8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-11, and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group B (claims 1-7, 9-11, and 13-16) in Paper No. 12, filed May 5, 2003, is acknowledged. The traversal is on the ground(s) that it was not established that searching all of the claims would constitute a burden. This is not found persuasive because the instant application was filed under 35 U.S.C. 371. As such, the application is subject to restriction under the rules regarding unity of invention, and burden of search is not a criterion in assessing unity of invention. The requirement is still deemed proper and is therefore made FINAL. As such, claims 8 and 12 are withdrawn from consideration.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-11, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a "[c]ombination that consists of at least one gestagen. . ." The transitional phrase "consists of" has the specific meaning of exactly the recited components. The

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limitation of “*at least one gestagen*” appears to allow for other components, conflicting with “consists of.” The claims are thus rendered vague and indefinite.

Claims 14-16 recite processes. However, the claim fail to recite any steps in those processes, thus rendering them vague and indefinite.

Further regarding claim 15, the phrase “preferably” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-7, 9, 10, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over BACKENSFELD et al (US 5,798,338).

The invention is drawn to a combination comprising a 14,17-C₂-bridged steroid and a cyclodextrin. Dependents include limitations regarding species of cyclodextrin, ratio of components and processes of complexing and pelletizing. Claim 9 recites the limitation "for birth control," but the intended use is not a patentable limitation.

BACKENSFELD teaches clathrates comprising steroidal sex hormones and cyclodextrins. The reference teaches that complexation of the steroid with the cyclodextrin results in decreased oxidative degradation of the steroid during storage. See col 1, lines 1-33. The reference further teaches the use of a variety of cyclodextrins and suggested ratios for the components. See col 2, lines 27-64. The reference also teaches the preparation of a pharmaceutical composition comprising such an inclusion complex in the examples. The steroid and cyclodextrin are co-precipitated to form a complex, followed by trituration with lactose. This composition is pressed into tablets.

The reference does not specifically exemplify the use of a 14,17-C₂-bridged steroid. However, the reference specifically suggests the use of these compounds. See col 1, lines 40-45.

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It would have been obvious to one having ordinary skill at the time the invention was made to prepare a composition comprising a clathrate of a cyclodextrin and a 14,17-C₂-bridged steroid. One of ordinary skill would reasonably expect success in preparing such a composition as BACKENSFELD had specifically suggested said composition. The artisan would be motivated to prepare such a clathrate to reduce oxidative degradation of the steroid. It would be within the scope of the artisan to optimize the ratio of the components with routine experimentation.

Claims 2, 3, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over BACKENSFELD et al (US 5,798,338) as applied to claims 1, 4-7, 9, 10, 15 and 16 above, and further in view of SCHOLLKOPF et al (WO 96/20209).

The invention is as set forth above. Dependents recite a particular genus of 14,17-C₂-bridged steroids and a method of birth control comprising the use of the instant compositions.

BACKENSFELD teaches as set forth above. The reference specifically suggests the use of 14 α ,17 α -ethanoestra-1,3,5(10)-triene-3,17 β -diol and 14 α ,17 α -ethanoestra-1,3,5(10)-triene-3,16 α ,17 β -triol. The reference does not teach the use of the compounds of formula I or the use of the compositions for contraception.

SCHOLLKOPF teaches the 14,17-C₂-bridged steroids of formula I. The reference discloses species including the compound recited in claim 3. See pages 4-6. The reference further teaches the use of these compounds in combination with the synthetic estrogens,

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14 α ,17 α -ethanoestra-1,3,5(10)-triene-3,17 β -diol or 14 α ,17 α -ethanoestra-1,3,5(10)-triene-3,16 α ,17 β -triol for the preparation of pharmaceuticals for use for contraception. See pages 7 and 8. The reference teaches administration of the compositions by a number of methods, including oral and parenteral. See page 9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition comprising any of the exemplified 14,17-C₂-bridged steroids of formula I and cyclodextrins. BACKENSFELD had taught the utility of preparing clathrates of 14 α ,17 α -ethanoestra-1,3,5(10)-triene-3,17 β -diol or 14 α ,17 α -ethanoestra-1,3,5(10)-triene-3,16 α ,17 β -triol for the resulting reduction in oxidative degradation. SCHOLLKOPF had taught that the 14,17-C₂-bridged steroids of formula I have utility in combination with either of these two compounds. One of ordinary skill would be motivated to prepare a composition comprising any exemplified compound of formula I, a cyclodextrin, and one of the synthetic estrogens set forth above for their additive effects. The artisan would reasonably expect stabilization of the 14,17-C₂-bridged steroids of formula I due to reduced oxidative degradation resulting in complexation with the cyclodextrin. It would be further obvious to use the thus prepared composition for the art-disclosed utility of effecting contraception and to select the appropriate method of administration.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Patent Examiner
June 9, 2003